

IN THE CLAIMS

Claim 1 (original): A process for the preparation of a polymer composite loaded with functioning matter directly in one step, wherein functioning matter is selected from mammalian, plant and bacterial subcellular, cellular or multicellular matter, liposomes, and aggregates and mixtures thereof wherein the process comprises contacting a polymer substrate and functioning matter with a plasticising fluid or mixture of plasticising fluids comprising a liquid or gaseous fluid which is capable of plasticising polymer in its natural state or in supercritical, near critical, dense-phase or subcritical state having fluid density in the range 0.001 g/ml up to 10 g/ml under plasticising conditions to plasticise and/or swell the polymer and incorporate the functioning matter, and releasing the plasticising fluid to obtain the polymer composite, wherein contacting is for a short contact time of 20 milliseconds up to 5 minutes at a pressure in the range  $1 \times 10^5$  to  $1 \times 10^8$  Nm $^{-2}$  (1 to 1000 bar) and a temperature in the range -200 to +500C, selected in manner that at least a proportion of functioning matter does not freeze or refreeze during processing, or if at a temperature at which freezing or refreezing may occur, that either matter is desiccated or a pressure constraint is applied whereby pressure is in a range having a maximum pressure less than  $1 \times 10^8$  Nm $^{-2}$  (1000 bar) throughout contact of functioning matter and plasticising fluid, whereby at least a proportion of functioning matter retains its function in the polymer composite.

Claim 2 (original): A process as claimed in Claim 1 with the proviso that it is carried out for very short contact time of plasticising fluid and functioning matter of less than 3 minutes.

Claim 3 (currently amended): A process as claimed in Claim 1 ~~any of~~ ~~Claims 1 and 2~~ wherein contacting is with cryopreserved or non cryopreserved functioning matter and is conducted at a temperature at least in the range +4 to +35°C and maximum pressure less than  $4 \times 10^7 \text{ Nm}^{-2}$  (400 bar) throughout contact of functioning matter and plasticising fluid.

Claim 4 (currently amended): A process as claimed in Claim 1 ~~any of~~ ~~Claims 1 to 3~~ contacting is with cryopreserved or non cryopreserved functioning matter and is conducted at a temperature at least in the range +4 to +35°C and maximum pressure less than  $2.75 \times 10^7 \text{ Nm}^{-2}$  (275 bar), for example in the range  $5 \times 10^5 \text{ Nm}^{-2}$  to  $75 \times 10^5 \text{ Nm}^{-2}$  (5 to 75 bar).

Claim 5 (currently amended): A process as claimed in Claim 1 ~~any of~~ ~~Claims 1 to 4~~ wherein contacting is with carbon dioxide as plasticising fluid wherein freezing or refreezing may take place during processing at least in the temperature range +4 to +35°C, and a pressure constraint is applied.

Claim 6 (currently amended): A process as claimed in Claim 1 ~~any of~~ ~~Claims 1 to 5~~ wherein at least 20% of functioning matter maintains function.

Claim 7 (currently amended): A process as claimed in Claim 1 ~~any of~~ ~~Claims 1 to 6~~ wherein plasticising conditions comprise a pressure in the range  $2 \times 10^5 \text{ Nm}^{-2}$  to  $4 \times 10^7 \text{ Nm}^{-2}$  (2 to 400 bar), more preferably  $5 \times 10^5 \text{ Nm}^{-2}$  to  $2.65 \times 10^7 \text{ Nm}^{-2}$  (5 to 265 bar).

Claim 8 (currently amended): A process as claimed in Claim 1 ~~any of~~ ~~Claims 1 to 7~~ wherein plasticising fluid includes carbon dioxide, di-nitrogen oxide, carbon disulphide, aliphatic C<sub>2</sub>-10 hydrocarbons such as ethane, propane, butane, pentane, hexane, ethylene, and halogenated derivatives thereof such as for example carbon

tetrafluoride or chloride and carbon monochloride trifluoride, and fluoroform or chloroform, C<sub>6</sub>-<sub>10</sub> aromatics such as benzene, toluene and xylene, C<sub>1</sub>-<sub>3</sub> alcohols such as methanol and ethanol, sulphur halides such as sulphur hexafluoride, ammonia, xenon, krypton, or a mixture thereof.

Claim 9 (currently amended): A process as claimed in Claim 1 any of Claims 1 to 8 wherein functioning matter is present in an amount with respect to polymer of 1x10<sup>-12</sup> wt% to 99.9 wt%.

Claim 10 (currently amended): A process as claimed in Claim 1 any of Claims 1 to 9 wherein functioning matter is selected from mammalian, plant and bacterial cells including (subcellular) organelles and aggregates thereof including pancreatic islet or liver spheroids and the like; and liposomes as carrier of sensitive matter.

Claim 11 (currently amended): A process as claimed in Claim 1 any of Claims 1 to 10 wherein functioning matter is selected from mammalian and plant prokaryotic and eukaryotic cells and mixtures and aggregates thereof; and liposomes as carrier of protein or enzymes.

Claim 12 (currently amended): A process as claimed in Claim 1 any of Claims 1 to 11 wherein functioning matter comprises mammalian cells selected from fibroblasts, fibrochondrocytes, chondrocytes, bone forming cells such as osteoblasts and osteoclasts, bone marrow cells, hepatocytes, cardiomyocytes, blood vessel forming cells, neurons, myoblasts, macrophages, microvascular endothelium cells and mixtures thereof and collagen, and liposomes.

Claim 13 (currently amended): A process as claimed in Claim 1 any of Claims 1 to 12 for the preparation of a polymer composite additionally comprising biofunctional material and loaded with

functioning matter wherein the process comprises in a first stage contacting biofunctional material selected from drugs and veterinary products, agrochemicals, human and animal health products, human and animal growth promoting, structural or cosmetic products, and absorbent materials for poisons and toxins and polymer and a plasticising fluid or a mixture of plasticising fluids under plasticising conditions to plasticise and/or swell the polymer and incorporate the biofunctional material.

Claim 14 (currently amended): Process as claimed in Claim 1 any of Claims 1 to 13 wherein polymer is selected from: polyesters including poly(lactic acid), poly(glycolic acid), copolymers of lactic and glycolic acid, copolymers of lactic and glycolic acid with poly(ethylene glycol), poly(*e*-caprolactone), poly(3-hydroxybutyrate), poly(*p*-dioxanone), poly(propylene fumarate); poly(ortho esters); polyanhydrides; Poly(amino acids); polyacetals; polyketals; polyorthoesters; Polyphosphazenes; azo polymers; synthetic Non-biodegradable Polymers selected from: Vinyl polymers including polyethylene, poly(ethylene-co-vinyl acetate), polypropylene, poly(vinyl chloride), poly(vinyl acetate), poly(vinyl alcohol) and copolymers of vinyl alcohol and vinyl acetate, poly(acrylic acid) poly(methacrylic acid), polyacrylamides, polymethacrylamides, polyacrylates, Poly(ethylene glycol), Poly(dimethyl siloxane), Polyurethanes, Polycarbonates, Polystyrene and derivatives; and Natural Polymers selected from carbohydrates, polypeptides and proteins.

Claim 15 (currently amended): A polymer composite comprising a polymer loaded with functioning matter selected from mammalian, plant and bacterial subcellular, cellular or multicellular matter and aggregates and mixtures thereof obtainable by the process as defined in Claim 1 any of Claims 1 to 14, wherein at least 20% of functioning matter has retained function in the polymer composite.

Claim 16 (currently amended): A polymer composite comprising a polymer loaded with functioning matter selected from mammalian, plant and bacterial subcellular, cellular or multicellular matter and aggregates and mixtures thereof as defined in Claim 1 ~~any of Claims 1 to 14~~ wherein functioning matter is non-established, ie is directly loaded functioning matter, and is not proliferated, grown, adhered or otherwise modified post loading, at least 20% of which has retained function in the polymer composite.

Claim 17 (currently amended): A polymer composite as claimed in Claim 15 ~~or 16~~ which is in granular or monolith form.

Claim 18 (currently amended): A polymer composite loaded with functioning matter selected from mammalian, plant and bacterial subcellular, cellular or multicellular matter and aggregates and mixtures thereof as claimed in Claim 15 ~~any of Claims 15 to 17~~, additionally comprising biofunctional materials, selected from drugs and veterinary products, agrochemicals, human and animal health products, human and animal growth promoting, structural or cosmetic products, and absorbent materials for poisons and toxins, suitably sized and shaped for a desired application.

Claim 19 (currently amended): A polymer composite, a scaffold thereof or the process for the preparation thereof as claimed in Claim 1 ~~any of Claims 1 to 18~~ for use as a support or scaffold for drug delivery, for use in bioremediation, as a biocatalyst or biobarrier for human or animal or plant matter, for use as a structural component, for example comprising the polymer and optional additional synthetic or natural metal, plastic, carbon or glass fibre mesh, scrim, rod or like reinforcing for medical or surgical insertion, for insertion as a solid monolith into bone or tissue, as fillers or cements for wet insertion into bone or teeth or as solid aggregates or monoliths for orthopaedic implants such as pins, or dental implants such as crowns etc.

Claim 20 (original): A process for preparing a polymer composite, a polymer composite, a scaffold, or the use thereof substantially as described in the description or illustrated in the Examples.